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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,115	11/30/2001	Nitya Anand	RLL-193US	4448

7590 11/05/2002

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EXAMINER
BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
1624	7

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/998,115	ANAND et al.
Examiner	**Art Unit**
Emily Bernhardt	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Nature of "amides" intended is not set forth in the claims nor the manner in which they are attached to the instant formula. Specification appears to give no guidance.

2. The same remark made in #1 also applies for the scope of "prodrugs" and "metabolites". For the former term, many functional groups are capable at least in theory to being derivatized but more than minimal experimentation would be required to determine what is and what is not within the instant scope since the choice of a suitable prodrug requires testing for rate of hydrolysis as well as in vivo stability and knowledge of an intended effect (i.e. modification of a undesirable property in the parent drug) and such is a function of the molecular structure of the parent drug as any textbook on prodrugs will confirm. For the latter term knowledge of degradation pathways of instant compounds in vivo would be required and nothing short of extensive testing (none identified) would be needed to determine what is and what is not within applicants' intended scope.

3.In claim 3 the compounds should be separated by semicolons not periods as they now are. A printer query would result if said claim was ever passed to issue.

4. For claims 4 and 7 there are no art recognized disorders known as "antagonzing" the a-1 adrenergic receptor. Such a phrase may denote a causative factor by which a particular disease may occur. What determines a host in need of antagonizing? One may have no visible symptoms and still be in need. It may turn out with further research that everyone is in need of such antagonism. How can one be sure that any use of compounds being claimed does not infringe claims 4 and 7? Such uncertainty in scope does not comply with the second paragraph of 35 USC 112.

5.Claims 9 and 10 are incomplete as recited since they do particualarly point out the invention by setting forth reactants,reaction conditions so that one reading the claims can ascertain its scope but rather resorts to Schemes in the specification which is improper. Note reliance on the specification to define claimed subject matter is permitted only under certain circumstances as discussed in Ex parte Fressola 27 USPQ 2d 1608.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Korgaonkar (ref. C7). The publication provided by applicants discloses several compounds within the instant scope for various pharmaceutical uses. See structure XI on p.874 and corresponding species, XIa-g listed in Table 1. Note the same process as embraced herein in claim 9 is taught for making said compounds. See last reaction on p.874. While the reference does not mention adrenergic antagonism, following the teachings of the reference one would be administering to a host an instant drug that targets at least said receptor and thus inherently performs the same function as claimed in 4 and 7. See Ex parte Novitski 26 USPQ 2d 1389 as well as the more recent decision, Integra LifeSciences v. Merck 50 USPQ 2d 1846.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,6,8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishizumi (US'078 or ref.C5). Both references appear to be describing the same type of compounds for uses such as anxiolytic, antiallergy agents and include the instant processes as can be seen in the use of starting reactants VI with VII or II with III in col.2 of US'078 or on page 2288 of the journal article. Closest compound (no.7 in ref. C5 and same species on lines 54-56 in col.9 of the US) differs in two respects, namely having butylene as a link between succinimide and piperazine ring and containing pyrimidyl vs. instant phenyl (and substituted phenyl) on the piperazine ring carbon. However Ishizumi teaches varying alkylene chains as a link including both butylene and propylene and exemplifies both types in many of the imide species described. See the definition of "B" in col.1 of the US patent. Also note that R3 in Ishizumi can be various phenyls as claimed herein .Thus one skilled in the art at the time the instant invention was made would have been motivated to prepare additional compounds taught by Ishizumi which are also embraced herein in view of the equivalency teachings outlined above and prepare such via the instant route(s).

Applicants' IDS filed 5/23/02 has been considered in part. Note that for ref. C13 only a cover page was provided and for ref. C16 the examiner could not ascertain its relevance since there are no formulas depicted and the text is all in the Cyrillic alphabet. An abstract or at least partial translation of the article is needed for consideration.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600